

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 2:08-cv-20011-HB

DEE HODAPP and MICHAEL HODAPP,

Plaintiffs,

v.

WYETH, AHP SUBSIDIARY HOLDING CORPORATION, and INDEVUS
PHARMACEUTICALS, INC. f/k/a INTERNEURON PHARMACEUTICALS, INC.,

Defendants.

**ANSWER OF WYETH AND AHP SUBSIDIARY HOLDING CORPORATION TO
COMPLAINT IN TORT FOR DAMAGES AND DEMAND FOR JURY**

Defendants Wyeth and AHP Subsidiary Holding Corporation¹ (collectively, “Wyeth”) hereby file their Answer to Plaintiffs’ Complaint in Tort for Damages and Demand for Jury (“Complaint”) and respond to the Complaint as follows:

PRELIMINARY STATEMENT

Plaintiffs’ Complaint improperly mixes factual averments with argumentative rhetoric so as to make admissions or denials of such averments difficult or impossible. Further, much of the Complaint consists of a selective recitation of historical facts and/or rumors, much of which is both irrelevant and inflammatory in tone and content. The Complaint also contains a selective recitation of statistics, scientific premises and conclusions, technical discussions, and

¹ On March 11, 2002, American Home Products Corporation (“AHPC”) changed its name to Wyeth. On June 30, 2001 Wyeth-Ayerst Laboratories Company merged into AHP Subsidiary Holding Corporation.

medical conclusions, few of which are identified as to source or supported by relevant data. It is not reasonably possible to identify the sources of such allegations so as to respond meaningfully. Finally, many of the allegations in the Complaint are overbroad, vague, or conclusory and include terms which are undefined and which are susceptible to different meanings. Accordingly, by way of a general response, all allegations are denied unless specifically admitted, and any factual averment admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, or speculations which are contained in the averment or in the Complaint as a whole.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

JURISDICTIONAL ALLEGATIONS

1. Wyeth is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and therefore denies the same.

2. Wyeth is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies the same.

3. Wyeth admits that it is a Delaware corporation with its principal place of business in New Jersey. Wyeth also admits that on March 11, 2002, the name of American Home Products Corporation ("AHPC") changed to Wyeth. Further, Wyeth admits that A.H. Robins Company, Inc. was merged into AHPC on or about August 3, 1998. Wyeth denies the remaining allegations in Paragraph 3.

4. Wyeth admits that AHP Subsidiary Holding Corporation is a corporation organized under the laws of the State of Delaware with its principal place of business in Delaware. Wyeth denies the remaining allegations in Paragraph 4.

5. Wyeth admits on information and belief that Indevus Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Lexington, Massachusetts, and that Indevus was formerly known as Interneuron Pharmaceuticals, Inc. Wyeth denies the remaining allegations in Paragraph 5.

6. The allegations in Paragraph 6 assert legal conclusions to which no response is required. To the extent a response is required, Wyeth admits that federal subject-matter jurisdiction exists. Wyeth further admits that Plaintiffs allege that the amount in controversy exceeds \$75,000, but denies that Plaintiffs are entitled to any relief whatsoever in this action, and denies the remaining allegations in Paragraph 6.

7. Wyeth admits that, prior to September 15, 1997, Wyeth-Ayerst Laboratories Division of AHPC (“WALD”) distributed and sold Pondimin and distributed, promoted, and sold Redux in the United States, including Colorado, to licensed health care providers for use in accordance with their FDA-approved prescribing information and subject to the precautions, warnings, and contraindications contained therein. Wyeth denies the remaining allegations in Paragraph 7.

GENERAL ALLEGATIONS

8. Wyeth admits that, prior to September 15, 1997, WALD distributed and sold Pondimin and distributed, promoted, and sold Redux in the United States, including Colorado, to licensed health care providers for use in accordance with their FDA-approved prescribing information and subject to the precautions, warnings, and contraindications contained therein. Wyeth denies the remaining allegations in Paragraph 8.

9. Wyeth admits that it voluntarily withdrew Pondimin and Redux from the market on September 15, 1997. Wyeth denies the remaining allegations in Paragraph 9.

10. Wyeth admits that, prior to September 15, 1997, WALD distributed and sold Pondimin and distributed, promoted, and sold Redux in the United States, including Colorado, to licensed health care providers for use in accordance with their FDA-approved prescribing information and subject to the precautions, warnings, and contraindications contained therein. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding what, if any, medications were ingested by Plaintiff Dee Hodapp, and therefore denies the same.

11. Wyeth denies the allegations in Paragraph 11.

12. Wyeth states that Plaintiff Dee Hodapp is a member of the class and her claims are therefore subject to the provisions of the Nationwide Class Action Settlement Agreement. Wyeth denies the remaining allegations in Paragraph 12.

13. Wyeth states that Plaintiff Dee Hodapp is a member of the class and her claims are therefore subject to the provisions of the Nationwide Class Action Settlement Agreement. Wyeth admits that Plaintiffs intend to amend the Complaint as alleged. Wyeth denies the remaining allegations in Paragraph 13.

RESPONSE TO FIRST CLAIM FOR RELIEF

(Strict Liability for Design Defect Against All Defendants)

14. Wyeth hereby incorporates its responses to the allegations in Paragraphs 1 through 13 as if fully set forth herein.

15. Wyeth admits that prior to September 15, 1997, WALD distributed, manufactured, and sold Pondimin and distributed, manufactured, promoted, and sold Redux in the United States for use in accordance with their FDA-approved prescribing information and subject to the precautions, warnings, and contraindications contained therein. Wyeth denies the remaining allegations in Paragraph 15.

16. Wyeth lacks knowledge and information sufficient to form a belief as to the truth of the allegations regarding what, if any, medications Plaintiff ingested. Wyeth denies the remaining allegations in Paragraph 16, including all subparts.

17. Wyeth denies the allegations in Paragraph 17.

18. Wyeth denies the allegations in Paragraph 18, including all subparts.

RESPONSE TO SECOND CLAIM FOR RELIEF

(Strict Liability for Failure to Warn Against All Defendants)

19. Wyeth hereby incorporates its responses to the allegations in Paragraphs 1 through 18 as if fully set forth herein.

20. Wyeth lacks knowledge and information sufficient to form a belief as to the truth of the allegations regarding what, if any, medications Plaintiff ingested. Wyeth denies the remaining allegations in Paragraph 20.

21. Wyeth denies the allegations in Paragraph 21.

22. Wyeth denies the allegations in Paragraph 22, including all subparts.

RESPONSE TO THIRD CLAIM FOR RELIEF

(Negligence Against All Defendants)

23. Wyeth hereby incorporates its responses to the allegations in Paragraphs 1 through 22 as if fully set forth herein.

24. Wyeth admits that prior to September 15, 1997, WALD manufactured, and sold Pondimin and Redux in the United States for use in accordance with their FDA-approved prescribing information and subject to the precautions, warnings, and contraindications contained therein. Wyeth states that the second phrase of Paragraph 27 states a legal conclusion to which no response is required. To the extent a response is required, Wyeth admits that it has only such duties as are imposed by law. Wyeth denies the remaining allegations in Paragraph 24.

25. Wyeth is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 and therefore denies the same.

26. Wyeth denies the allegations in Paragraph 26, including all subparts.

27. Wyeth denies the allegations of Paragraph 27, including all subparts.

**RESPONSE TO FOURTH CLAIM FOR RELIEF
(Breach of Warranty Against All Defendants)**

28. Wyeth hereby incorporates its responses to the allegations contained in Paragraphs 1 through 27 as if fully set forth herein.

29. Wyeth denies the allegations in Paragraph 29.

30. Wyeth denies the allegations of Paragraph 30, including all subparts.

**RESPONSE TO FIFTH CLAIM FOR RELIEF
(Fraud Against All Defendants)**

31. Wyeth hereby incorporates its responses to the allegations in Paragraphs 1 through 30 as if fully set forth herein.

32. Wyeth denies the allegations in Paragraph 32.

33. Wyeth denies the allegations in Paragraph 33.

34. Wyeth states that the documents and publications referenced in Paragraph 34 speak for themselves. Wyeth denies the remaining allegations in Paragraph 34, including all subparts.

35. Wyeth states that the documents referenced in Paragraph 35 speak for themselves. Wyeth denies the remaining allegations in Paragraph 35, including all subparts.

36. Wyeth denies the allegations in Paragraph 36.

37. Wyeth denies the allegations in Paragraph 37.

38. Wyeth denies the allegations in Paragraph 38.

39. Wyeth denies the allegations in Paragraph 39.

40. Wyeth denies the allegations in Paragraph 40.

41. Wyeth denies the allegations in Paragraph 41.

42. Wyeth denies the allegations in Paragraph 42.

43. Wyeth denies the allegations in Paragraph 43.

44. Wyeth denies the allegations in Paragraph 44, including all subparts.

**RESPONSE TO SIXTH CLAIM FOR RELIEF
(Misrepresentation Restatement of Torts § 403B Against All Defendants)**

45. Wyeth hereby incorporates its responses to the allegations contained in Paragraphs 1 through 44 as if fully set forth herein.

46. Wyeth admits that prior to September 15, 1997, WALD distributed, manufactured, and sold Pondimin and distributed, manufactured, promoted, and sold Redux in the United States for use in accordance with their FDA-approved prescribing information and subject to the precautions, warnings, and contraindications contained therein. Wyeth denies the remaining allegations in Paragraph 46.

- 47. Wyeth denies the allegations in Paragraph 47.
- 48. Wyeth denies the allegations in Paragraph 48.
- 49. Wyeth denies the allegations in Paragraph 49.
- 50. Wyeth denies the allegations in Paragraph 50.
- 51. Wyeth denies the allegations in Paragraph 51, including all subparts.

**RESPONSE TO SEVENTH CLAIM FOR RELIEF
(Loss of Consortium Against All Defendants)**

52. Wyeth hereby incorporates its responses to the allegations contained in Paragraphs 1 through 51 as if fully set forth herein.

53. Wyeth is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 53 and therefore denies the same.

54. Wyeth denies the allegations in Paragraph 54.

GENERAL DENIAL

All allegations contained in the Complaint not heretofore specifically admitted, denied, or explained, are here and now denied.

AFFIRMATIVE DEFENSES²

FIRST DEFENSE

Plaintiffs' causes of action are barred in whole or in part by the applicable statute of limitations, to the extent not otherwise provided in § IV.D.3.c, § IV.D.4.c, and/or § VII.B.4 of the Nationwide Class Action Settlement Agreement with American Home Products Corporation (the "Settlement Agreement").

² Wyeth asserts the following affirmative defenses in an abundance of caution. In so doing, Wyeth does not intend to nor does it admit or concede that all of the affirmative defenses listed below are affirmative defenses for which it carries the burden of proof.

SECOND DEFENSE

Plaintiff Dee Hodapp is a member of a class which is subject to the provisions of a Nationwide Class Action Settlement Agreement with American Home Products Corporation, approved by the United States District Court for the Eastern District of Pennsylvania. By reason of that Settlement Agreement, Plaintiffs' causes of action are barred in whole or in part by the doctrines of merger, bar, collateral estoppel, *res judicata*, release, discharge, accord and satisfaction, and covenant not to sue and are barred by an injunction entered by that Court.

THIRD DEFENSE

Plaintiffs' causes of action are barred in whole or in part by the doctrines of laches, waiver and estoppel, to the extent not otherwise provided in § IV.D.3.c, § IV.D.4.c, and/or § VII.B.4 of the Settlement Agreement.

FOURTH DEFENSE

Plaintiff's causes of action are barred because Pondimin and Redux were not dangerous to a degree beyond that which would be expected by an ordinary user or consumer.

FIFTH DEFENSE

Plaintiffs' alleged damages were caused entirely or in part by the contributory or comparative negligence or fault of the Plaintiff, which negligence or fault is a total or partial bar to Plaintiffs' claims for damages herein.

SIXTH DEFENSE

To the extent Plaintiffs' negligence was less than the negligence of Wyeth (any such negligence being denied), Plaintiffs' recovery must be diminished in proportion to the negligence of Plaintiff.

SEVENTH DEFENSE

The damages alleged by Plaintiffs were caused or proximately caused by some person or third party other than Wyeth for whom Wyeth is not legally responsible.

EIGHTH DEFENSE

Plaintiffs' alleged damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of, or product placed in the stream of commerce by, Wyeth. Plaintiff suffered no physical injury caused by, arising from, or relating to Pondimin or Redux.

NINTH DEFENSE

Plaintiffs' alleged damages were not proximately caused by any act or omission of Wyeth.

TENTH DEFENSE

Plaintiffs' alleged damages were the result of pre-existing conditions which were unrelated to any conduct of, or product placed in the stream of commerce by, Wyeth.

ELEVENTH DEFENSE

Plaintiffs' alleged damages were the result of an idiosyncratic reaction that Wyeth could not reasonably foresee.

TWELFTH DEFENSE

Plaintiff was not a foreseeable user of the products.

THIRTEENTH DEFENSE

Plaintiffs' damages, if any, and if they were caused by Pondimin or Redux, were caused in whole or in part by misuse or unintended use of the products.

FOURTEENTH DEFENSE

Plaintiffs' damages, if any, were caused by changes and/or alterations to products made by persons not within Wyeth's control.

FIFTEENTH DEFENSE

Wyeth provided adequate warnings and complete warnings to Plaintiff's prescribing physicians. Therefore, any claims by Plaintiffs for inadequate warnings are controlled by, and barred under, the learned intermediary doctrine.

SIXTEENTH DEFENSE

Plaintiffs' causes of action are barred, in whole or in part, by Plaintiffs' failure to assert an alternative, safer design under the circumstances for Pondimin and/or Redux.

SEVENTEENTH DEFENSE

Plaintiffs' product liability causes of action are barred because the benefits of Pondimin and Redux outweighed their risks.

EIGHTEENTH DEFENSE

Plaintiffs' product liability causes of action are barred because the relevant product was consistent with or exceeded consumer expectations.

NINETEENTH DEFENSE

Based on the state of scientific, medical, and technological knowledge at the time Pondimin and Redux were marketed, they were reasonably safe for their normal and foreseeable uses.

TWENTIETH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Wyeth complied with all

applicable statutes and with the requirements and regulations of the Food and Drug Administration.

TWENTY-FIRST DEFENSE

Plaintiffs' claims under Colorado law are barred by the doctrine of federal preemption.

TWENTY-SECOND DEFENSE

Plaintiffs' claims against Wyeth are barred under Section 402A, comments K and J of the Restatement (Second) Of Torts and Sections 2, 4, and 6 et seq. of the Restatement (Third) Of Torts: Products Liability.

TWENTY-THIRD DEFENSE

The damages, if any, recoverable by Plaintiffs must be reduced by any amount of damages legally caused by Plaintiffs' failure to mitigate such damages in whole or part.

TWENTY-FOURTH DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

TWENTY-FIFTH DEFENSE

Wyeth expressly denies that any third party engaging in the acts alleged by Plaintiffs was acting as Wyeth's agent or servant, at the instruction of Wyeth or within Wyeth's control. Therefore, Plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

TWENTY-SIXTH DEFENSE

Plaintiffs' claims may be barred by the doctrine of accord and satisfaction.

TWENTY-SEVENTH DEFENSE

Plaintiffs' claims should be dismissed due to improper venue, if Plaintiffs are not in fact

residents of Colorado.

TWENTY-EIGHTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statute of limitations, statutes of repose, estoppel, laches, and/or other equitable doctrines.

TWENTY-NINTH DEFENSE

Neither Plaintiff nor her respective physicians were induced to prescribe or use Pondimin or Redux based on any material representations or misrepresentations of Wyeth.

THIRTIETH DEFENSE

Plaintiffs did not rely on any express or implied warranty allegedly made by Wyeth.

THIRTY-FIRST DEFENSE

Plaintiffs are not in privity of contract with Wyeth, and therefore, cannot maintain an action in warranty against Wyeth.

THIRTY-SECOND DEFENSE

Wyeth hereby gives notice that it intends to rely upon any other defense that may become available or appear during the discovery proceedings in the case and hereby reserves the right to amend this Answer to assert any such defense. Wyeth also reserves the right to assert other and related defenses as may become available upon a determination of the law applicable to the action or any part thereof or claim therein.

THIRTY-THIRD DEFENSE

This action is subject to the proportionate fault provisions of C.R.S. § 13-21-111.5 of the Colorado Revised Statutes, including, without limitation, the requirement of § 13-21-111.5(3)(a) that the finder of fact may consider the degree or percentage of negligence or fault of a person

not a party to the action.

THIRTY-FOURTH DEFENSE

Plaintiffs have failed to allege fraud with sufficient particularity.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

Wyeth admits that Plaintiffs seek the relief requested, but denies Plaintiffs are entitled to any judgment against Wyeth whatsoever, including any relief requested in Plaintiffs' prayer for relief.

WHEREFORE, Wyeth, having fully answered the Plaintiffs' Complaint, prays that Plaintiffs take nothing by this suit and demands as follows:

1. That the Complaint be dismissed with prejudice on the merits;
2. That Wyeth recovers their costs and disbursements herein expended;
3. That Wyeth be granted leave to file an amended pleading upon conclusion of reasonable discovery, if necessary;
4. That Wyeth receive a trial by jury of all issues; and
5. That Wyeth be accorded all other relief to which they now or hereafter appear to be entitled.

Respectfully submitted,

/s/ Meaghan M. Shaughnessy

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Date: December 1, 2008

CERTIFICATE OF SERVICE

The undersigned certifies that on this 1st day of December, 2008, a copy of the foregoing Answer of Wyeth and AHP Subsidiary Holding Corporation to Plaintiff's Complaint in Tort for Damages and Demand For Jury, was served upon counsel for Plaintiff in the manner indicated below. This document was also electronically filed and served on all parties via ECF, and is available for viewing and downloading from the ECF system.

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